MAY 2 5 2012

510(k) Summary

K111049

Submission Date: April 10, 2011

1. **Submitter Information:** AEGIS Regulatory, Inc. - Robert T. Wagner
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Knoxville, TN 37922
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For Manufacturer: MedTek Lighting, Inc.
Attn: Mr. Gary Richardson
3 Depot St.
Hudson Falls, NY 12839
Tel.: 518-747-3310

2. **General Information:**

2.1 Classification Name: FTC – Ultraviolet lamp for dermatologic disorders

2.2 Common/Usual Name: UV Biotek Mobile- Lite and Versa- Lite

2.3 Proprietary Names: UV Biotek Mobile-Lite model 600 and Versa-Lite model 1400

2.4 Classification: Class II

2.5 Classification Number: 878.4630

2.6 Product Code: FTC

3. **Device Description:**

The UV Biotek Mobile-Lite model 600 is a lightweight metal box containing six Philips 15-Watt TL-01 nUVB (narrowband UVB) lamps, configured as a suitcase for portability, designed to be placed either on a table or a stand for easy exposure to feet, lower legs, hands and lower arms. A remote control timer module is used to program exposure times and dosages.

The UV Biotek Versa-Lite model 1400 is a phototherapy device, freestanding support with 3 lighting panels containing a total of 14 Philips TL20W/01 (narrowband UVB) lamps. The panels can be used simultaneously or individually, depending on treatment needed. System dimensions: 83" high, 27" deep, and 28" wide – when system panels are in start position.

4. Intended Use:

- The UV Biotek Mobile-Lite model 600 is for individuals who require specific Ultraviolet radiation therapy for diagnosed skin disorders and is used for the treatment of psoriasis, vitiligo, and atopic dermatitis (eczema) on all skin types (I - VI)

- The UV Biotek Versa-Lite model 1400 is for individuals who require specific Ultraviolet radiation therapy for diagnosed skin disorders and is used for the treatment of psoriasis, vitiligo, and atopic dermatitis (eczema) on all skin types (I - VI)

5. Substantial Equivalence to Predicate Device(s):

These devices are substantially equivalent to the following predicate devices, which are currently in safe and effective commerce:

1. K050695 – Flex Controlled Phototherapy (Daavlin)
2. K872649 – Hand/Foot UVA/UVB (National Biological)
3. K933952 – Phototherapeutix 800 (Avex, now Medtek Lighting)
4. K031800 - Solrx 500 Series (Solarc)
5. K904427 – Panosol II UVB- 206 (National Biological)

Please see attached Predicate Comparison Chart for detailed information.

Predicate Comparison Chart

Device	FLEX CONTROLLED PHOTOTHERA	Hand/Foot UVA/UVB	Solrx 500 Series
Company	Daavlin Distributing Company	National Biological	Solarc
"K" Number	K050695	K872649	K031800
Indications for Use	For the treatment of psoriasis, vitiligo, and atopic dermatitis (eczema) on all skin types (I - VI)	For individuals who require specific Ultraviolet radiation therapy for diagnosed skin disorders.	For individuals who require specific Ultraviolet radiation therapy for diagnosed skin disorders.
Power	120v 60 hz	120v 60 hz	120v 60 hz
Treatment Spot Size	Hand and Foot	Hand and Foot 3-4 Square feet	Spot, Hand, and Foot 2 square feet
Dimensions of Device	27.5" x 35" (HW) panels fully open	24"W x 12 ¾"H x 20 "D	15" x 27.5" (HW)
Housing Materials and Construction	Steele safety shield, UV lamps, timer, googles	Steele safety shield, UV lamps, timer, googles	Steele safety shield, UV lamps, timer, googles
Energy Source	12v Power Adapter	12v Power Adapter	12v Power Adapter
Treatment Regime	Prescribed by physician	Prescribed by physician	Prescribed by physician
Target Population	People diagnosed with psoriasis, vitiligo, and eczema	People diagnosed with skin disorders	People diagnosed with skin disorders
Number of Lamps Model Number Wattage Output UVB (W) Lamp Voltage Lamp Current Length of Lamp	8 Narrowband UVB Lamps TL 20W/01RS 20w 2.3 57 0.37 24"	8 Narrowband UVB Lamps **Philips** TL-01 20/40/100 2.3/4.6/17.7 57/104/126 .37/.43/.97 24"	5 Narrowband UVB Lamps PL-L36W/01 Lamp Wattage 36w 6.2 106 0.43 24"
Light Source	Fluorescent Ultra Violet	Fluorescent Ultra Violet	Fluorescent Ultra Violet
Wavelength Range	311 nm (Narrow Band UVB), 305 nm (Broad Band UVB) and 350 nm (UVA)	311 nm (Narrow Band UVB)	311 nm (Narrow Band UVB)
Product Codes	FTC	FTC	FTC

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Phototherapeutix 800	MedTek UV Biotek Mobile Lite	MedTek UV Biotek Versa Lite	Panosol II UVB-206
Avex, now Medtek Lighting	Medtek Lighting	Medtek Lighting	National Biological
K993952	K	K	K904427
For individuals who require specific Ultraviolet radiation therapy for diagnosed skin disorders.	For the treatment of psoriasis, vitiligo, and atopic dermatitis (eczema) on all skin types (I - VI)	For the treatment of psoriasis, vitiligo, and atopic dermatitis (eczema) on all skin types (I - VI)	For the treatment of psoriasis, vitiligo, and atopic dermatitis (eczema) on all skin types (I - VI)
120v 60 hz	120v 60 hz	120v 60 hz	120v 60 hz
Full Body	Spot, Hand, and Foot 2-3 feet	Spot, Hand, and Foot 2-3 feet	Spot, Hand, and Foot 2-3 feet
8" x 38" x 83" (HWD)	Open- 18" x 34 1/2" x 17 1/2" (HWD)	27.5" x 35" (HW) panels fully open	29-1/2"W x 25-1/2"H x 4-12"D (11-1/2"D with stand)
Steele safety shield, UV lamps, timer, googles	Steele safety shield, UV lamps, timer, googles	Steele safety shield, UV lamps, timer, googles, stand & wheels	Steele safety shield, UV lamps, timer, googles, stand & wheels
12v Power Adapter	12v Power Adapter	12v Power Adapter	12v Power Adapter
Prescribed by physician	Prescribed by physician	Prescribed by physician	Prescribed by physician
People diagnosed with skin disorders	People diagnosed with psoriasis, vitiligo, and eczema	People diagnosed with psoriasis, vitiligo, and eczema	People diagnosed with psoriasis, vitiligo, and eczema
8 Narrowband UVB Lamps Philips TL20W/01 Lamp Wattage 20w 2.3 57 0.37	6 NarrowBand UVB Lamps Philips TL101 Lamp Wattage 15w 2.3 48 0.23 24"	14 NarrowBand UVB Lamps Philips TL20W/01 Lamp Wattage 20w 2.3 57 0.37 24"	8 Narrow Band UVB Lamps Philips TL20W/01 Lamp Wattage 20w 2.3 57 0.37 24"
Fluorescent Ultra Violet	Fluorescent Ultra Violet	Fluorescent Ultra Violet	Fluorescent Ultra Violet
311 nm (Narrow Band UVB)	311 nm (Narrow Band UVB)	311 nm (Narrow Band UVB)	311 nm (Narrow Band UVB)
FTC	FTC	FTC	FTC

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6. Substantial Equivalence Discussion:

These devices have the same technological characteristics as the cited predicate devices. Both devices use the same design, material, and energy source as the cited predicates.
After an analysis of the safety, indications, intended uses, performance features, design materials, chemical composition, energy source, power output, technological properties, treatment areas, treatment regimes and methods of operation, the manufacturer believes that no significant differences exist between the device and the predicates listed in section 5 of this summary.
Therefore substantial equivalency is requested.

7. Performance Standards:

These devices have been tested under and are in compliance with performance standards that have been established for such devices under Section 878 of the Federal Food, Drug, and Cosmetics Act. All electrical and radiological products made by the applicant have been OSHA/NRTL listed, and have received constituent marks and are found to be in compliance with EN/IEC 60601-1-1 and EN/IEC 60601-1-2.

8. Biocompatibility:

The patient contact material on the Mobile Lite and Versa Lite is Acrylic and is the same material used in the cited predicate devices.
The biocompatibility of this material is well known and accepted.

9. Sterilization / Use:

The Mobile Lite and Versa Lite is a non-sterile device, and therefore this section is not applicable. Cleaning Instructions are listed in the User's Manual.

Conclusion

After an analysis of the safety, indications, intended uses, performance features, design materials, chemical composition, energy source, power output, technological properties, treatment areas, treatment regimes and methods of operation, the manufacturer believes that no significant differences exist between the device and the predicates listed in section 5 of this summary.
Therefore substantial equivalency is requested.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 25 2012

Medtek Lighting Corporation
% Aegis Regulatory, Incoporated
Mr. Robert Wagner
CEO
1131 Anthem View Lane
Knoxville, Tennessee 37922

Re: K111049
Trade/Device Name: UV Biotek-Mobile-Lite model 600 and Versa-Lite model 1400
Regulation Number: 21 CFR 878.4630
Regulation Name: Ultraviolet lamp for dermatologic disorders
Regulatory Class: Class II
Product Code: FTC
Dated: May 14, 2012
Received: May 21, 2012

Dear Mr. Robert Wagner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K111049

Device Names: UV Biotek- Mobile-Lite model 600 and Versa-Lite model 1400

Indications For Use – Part 878.4630:

The UV Biotek Mobile-Lite model 600 is for individuals who require specific Ultraviolet radiation therapy for diagnosed skin disorders and is used for the treatment of psoriasis, vitiligo, and atopic dermatitis (eczema) on all skin types (I - VI)

The UV Biotek Versa-Lite model 1400 is for individuals who require specific Ultraviolet radiation therapy for diagnosed skin disorders and is used for the treatment of psoriasis, vitiligo, and atopic dermatitis (eczema) on all skin types (I - VI)

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111049